

AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions, and listings, of claims in the present application.

Listing of Claims:

1. (Currently Amended) A method for determining the concentration of circulating total DNA in a plasma sample specimen from a cancer patient, a subject with cancer susceptibility or at risk of developing cancer, which comprises:

- 1) extracting the DNA from the plasma specimen sample to create a target DNA sample preparation;
- 2) adding to the target DNA sample preparation: a) a mixture of oligonucleotide primers suitable for PCR amplification of a fragment of the human telomerase reverse transcriptase (hTERT) gene, wherein said fragment of the hTERT gene is from nucleotide position 13059 to nucleotide position 13156 of the sequence of GenBank accession no. AF128893, and b) an oligonucleotide probe, having at least one quencher and one reporter fluorophore at the 3' and 5' ends, able to anneal to a sequence within the region delimited by the primers, in suitable conditions for carrying out a PCR reaction,
- 3) adding a heat-stable DNA polymerase with 5'-3' hexonuclease activity and amplifying the hTERT gene fragment;
- 4) measuring the produced fluorescence;
- 5) ~~determining the amount of~~ quantifying the hTERT DNA copy number in the target DNA sample ~~sample concentration in the DNA preparation by interpolation of~~ interpolating a calibration curve ~~ealeulated~~ created with known amounts of DNA, wherein the concentration of circulating total DNA in a plasma sample is determined by quantification of hTERT copy number.

2. (Cancelled).

3. (Previously Presented) A method as claimed in claim 1, which further comprises comparing the concentration of circulating DNA to a reference concentration.

4. (Previously Presented) A method according to claim 3, wherein the reference concentration is from 9 to 25 ng/ml.

5. (Cancelled).

6. (Previously Presented) A method according to claim 1, wherein said fragment of the human telomerase reverse transcriptase (hTERT) gene is amplified using SEQ ID NO: 1 and 2 as the primers forward and reverse, respectively, and SEQ ID NO: 3 as the probe.

7. (Previously Presented) A method as claimed in claim 1, for the early diagnosis, prognosis or clinical monitoring of cancer patients.

8. (Previously Presented) A method as claimed in claim 1, for the evaluation of the risk of developing cancer in healthy individuals or individuals with familiar cancer susceptibility.

9. (Original) A method as claimed in claim 8, for the evaluation of the risk of cancer development in smokers.

10. (Original) A method as claimed in claim 1, wherein said cancer is lung, colon-rectum, head and neck, liver or pancreas cancer.

11. (Original) A method as claimed in claim 10, wherein said cancer is lung carcinoma.